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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,705

04/12/2007

Jurgen Dannenmaier

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,705	<b>Applicant(s)</b> DANNENMAIER ET AL.	
	<b>Examiner</b> Philip R. Wiest	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/9/06, 7/12/10</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Species C: Figure 3 in the reply filed on 4/29/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). No claims are withdrawn from further consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 recites the limitation "the second end of the fourth conduit and the first end of the fifth conduit" in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 29, 30, 45, 48-55, and 60-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindsay et al. (US 4,433,971).
3. With respect to Claim 29, Lindsay et al (hereafter 'Lindsay') teaches a fluid distribution module comprising a degassing device 11, said degassing device comprising a first chamber 58 having an inlet for a liquid and a second chamber 184 having an opening 188 that is closed by a hydrophobic membrane 194 and an outlet 62 for discharging the liquid. The first chamber partially extends within the second chamber and communicates therewith through an upper passageway (203, 204), the second chamber having an upstream portion that extends above said passageway and a downstream portion extending below the passageway (see Figure 2). Lindsay further teaches a connecting structure having a first conduit 58 and a second conduit 64 disposed therein. The first conduit 58 comprises a first end capable of connection to a discharge tube from an oxygenator (from discharge tube 22) and a second end connected to the inlet of the first chamber. The second conduit 64 comprises a first end capable of connection to the outlet 64 of the second chamber and a second end for connection to a blood return tube (66, 76) to a patient.
4. With respect to Claim 30, Lindsay teaches a third conduit 36 capable of connection between a post-dilution infusion tube and to the second end of the first conduit 56.
5. With respect to Claims 45 and 60, the upper rim 204 of the passageway between the first and second chambers is substantially angled (Column 5, Lines 7-13), such that

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the downstream part of the second chamber asymmetrically surrounds the upper part of the first chamber.

6. With respect to Claims 48 and 61, Lindsay teaches that the passageway (203, 204) from the first chamber to the second chamber of the degassing device comprises a cross section that is smaller than the cross section of the second chamber.

7. With respect to Claims 49 and 62, the second chamber is disposed around the first chamber. Further, the passageway comprises an angled rim 204, such that blood spills over to the side opposite from the outlet 62, then flows around the cylindrical passageway to the outlet (column 5, lines 7-13). Therefore, blood will flow through the second chamber in a circular manner (i.e. tangential to the hydrophobic filter).

8. With respect to Claims 50, 53, and 64, the second chamber is disposed circumferentially around the first chamber, such that the degassing device and associated flow path are substantially umbrella-shaped. Fluid that overflows from the first chamber will flow into the second chamber.

9. With respect to Claim 52, the first chamber has a downstream portion having a cross-sectional that is substantially the same as at least a portion of the cross-section of the passageway (203, 206) between the first and second chambers.

10. With respect to Claims 54 and 65, Lindsay teaches that the second chamber comprise a dome-shaped top, such that the chamber has a large cross-sectional diameter adjacent the passageway (206, 203) and a narrow cross-sectional diameter at the top portion thereof. The second chamber extends upward through opening 188,

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such that the cross sectional diameter adjacent the filter is substantially smaller than that of the passageway.

11. With respect to Claim 55, the outlet 62 of the second chamber is disposed at the lowest point thereof.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 41-44 and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay. Lindsay teaches the device substantially as claimed, but does not specifically teach the claimed cross-sectional diameter ratios between the first and second chambers of the degassing device (and the resulting flow rates). However, it has been held that the mere optimization of a prior art device through routine experimentation does not constitute a patentable improvement in the art (see MPEP § 2144.05). In this case, Lindsay clearly suggests a variety of diameter ratios to provide optimal fluid flow rate from the first chamber to the second chamber Column 4, Line 61 through Column 5, Line 34). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the diameter ratio of the first and second chambers of the degasser device in order to provide an optimal flow velocity in the second chamber, thereby maximizing the speed and effectiveness of air removal.

13. Claims 31-33 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Buckberg (US 5,011,469). Lindsay teaches the device substantially as claimed, and further teaches that the system comprises a withdrawal line 20 connecting the patient access point to the pump 28 and an infusion line 30 for infusing a medicament into the blood. Lindsay, however, is silent on whether the withdrawal line comprises pumps on *both sides* of the oxygenator (such that the withdrawal conduit comprises a fourth conduit extending from the patient access to a pump, and a fifth conduit that extends from said pump to said oxygenator).

However, it is commonplace in the art of extracorporeal treatment that a plurality of pumps may be used to drive fluid through the system. Buckberg (hereafter Buckberg '469) teaches an extracorporeal cardioplegia delivery system for oxygenating blood comprising a withdrawal conduit (29, 40), a withdrawal pump 18, an oxygenator 20, a cardioplegia pump 24, and an infusion lumen. The withdrawal pump 18 is configured to apply a negative pressure to the withdrawal conduit, such that blood is sucked through the conduit. Once blood reaches the pump 18, it applies positive pressure to move the blood forward through the oxygenator. Once the blood passes the oxygenator and mixes with other fluids, the cardioplegia pump 24 will reinfuse the fluid into the body. Specifically, Buckberg '469 teaches that the use of a withdrawal pump 18 is commonplace because it allows for separate flow rates on either sides of the oxygenator. This is crucial to the functionality of a cardioplegia delivery device because other fluids are being added to the blood (as is the case in both Buckberg '469 and

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Lindsay). See Column 6, Lines 10-30 and Column 10, Line 66 through Column 11, Line 19). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to place a withdraw pump upstream of Lindsay's oxygenator (such that the withdrawal line comprises the fourth conduit and fifth conduit as discussed above), in order to provide a means for withdrawing blood from the patient at a rate independent of the patient's physiological blood pressure.

14. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Strauss et al. (US 5,837,905). Lindsay teaches the device substantially as claimed, but does not specifically teach that the system is connected by means of a periphery with a plurality of sockets attached thereto. Strauss et al (hereafter 'Strauss') teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having a plurality of sockets onto which tubing segments are mounted. This system allows a plurality of disposable flow conduits to be attached to reusable elements of a blood treatment system, such as blood pumps and sensors (see Abstract and entire disclosure). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the extracorporeal treatment device of Lindsay with Strauss' unitary cassette having a plurality of sockets for the connection of fluid tubing in order to provide a well known means for organizing blood tubing and reusing expensive elements of a blood treatment system.



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15. With specific regard to the claimed laterally-extending loop, it has been held that the mere rearrangement of parts does not constitute a patentable improvement in the art when said rearrangement does not result in a non-obvious improvement (see MPEP § 2144.04). In this case, Lindsay teaches the claimed device except for the use of a periphery with a plurality of sockets attached thereto, and Strauss reasonably suggests that a cardioplegia system may be mounted on a cassette with tubes mounted at the appropriate positions. It would have been obvious to rearrange the specific orientation of the tubing such that a lateral loop is formed to connect respective inlets and outlets, because doing so would not substantially change the operation of the device.

16. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Bringham et al. (US 4,698,207). Lindsay teaches the device substantially as claimed, and further teaches that the second portion of the degassing device comprises an outer cylindrical wall surrounding the first chamber. Lindsay, however, does not specifically teach that the outer cylindrical wall is beveled. Bringham et al. (hereafter 'Bringham') teaches an integrated oxygenator and gas removal device wherein blood is inserted tangentially around the inlet to the oxygenator. Bringham specifically teaches that tangential flow is commonly used because it quickly dislodges air bobbles from blood due to buoyancy and centrifugal forces (Column 8, Lines 3-9). Further, Bringham teaches that the walls of the tangential flow path are beveled, such that a narrow annular opening is formed, thereby further promoting the separation of gas and blood (Column 5, Lines 1-13). It would have been obvious to one of ordinary

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skill in the art at the time of invention to modify the cylindrical outer flow path of Lindsay with Bringham's beveled, tangential path in order to provide for more efficient separation of air bubbles from blood.

17. Claims 51 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Buckberg (US 5,643,191). Lindsay teaches the device substantially as claimed, wherein air rises to the top of the second chamber such and to the top of outlet tube 190 to contact the hydrophobic membrane. Lindsay, however, does not specifically teach that the hydrophobic membrane is disposed adjacent the accumulation of gas bubbles. Buckberg (hereafter Buckberg '191) teaches a cardioplegia treatment system comprising a degassing chamber for removing gas from blood. Blood passes into a first chamber, then rises into a second chamber. Once in the second chamber, gas bubbles rise to the top portion thereof, where they contact a hydrophobic membrane 68. Further, the second chamber comprises a bubble screen that forces gas bubbles to the top of the chamber. The hydrophobic membrane has a porosity such that air is allowed to pass therethrough, but liquids are substantially prevented from passing. Further, a one-way pressure-activated valve is disposed distally of the membrane, such that non-sterile outside air does not come into contact with the blood. This arrangement will result in a constant stream of gas bubbles moving toward the top of the second chamber. It is the examiner's position that this configuration provides substantially the same functionality as the claimed device. It would have been obvious to one of ordinary skill in the art at the time of invention to

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modify the degassing device of Lindsay with the hydrophobic membrane and bubble screen of Buckberg in order to provide an alternate means for removing gas from blood, thereby preventing gas bubbles from being infused into the body.

18. Claims 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Buckberg '469, and further in view of Strauss. Lindsay and Buckberg '469 reasonably suggest the device substantially as claimed, but do not specifically teach that the system comprises a plurality of pressure measuring chambers corresponding to each of the flow paths. Strauss teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having pressure-sensing cells (38, 40, 46, 48) attached thereto. The pressure-sensing cells comprise a first compartment that allows fluid to flow through the conduits, and a second compartment that is configured to determine the pressure of the fluid in said conduits. The first and second compartments of the pressure sensors are separated by membrane diaphragms (Column 7, Lines 40-61). Strauss teaches that it is commonplace in the art to dispose pressure sensors along flow paths in a medical fluid cassette because doing so allows the speed of the pumps to be adjusted by the controller in real time to vary the ratio of blood and crystalloid (see Abstract and entire disclosure). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the blood treatment device of Lindsay and Buckberg '469 with Strauss' membrane-type pressure sensors in order to provide a well-known means

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for monitoring and controlling fluid flow at based on pressures at different points in the fluid circuit.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/  
Examiner, Art Unit 3761  
/Leslie R. Deak/  
Primary Examiner, Art Unit 3761